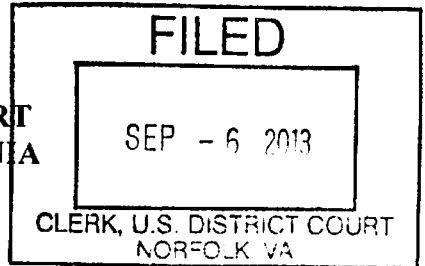


IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
NORFOLK DIVISION



LIFENET HEALTH,  
A Virginia Corporation

Plaintiff,

v.

LIFECCELL CORPORATION,  
A Delaware Corporation

Defendant.

Civil Action No. 2:13CV486

**JURY TRIAL DEMANDED**

**COMPLAINT**

LifeNet Health ("LifeNet"), by and through its undersigned counsel, states as follows for its complaint against the defendant, LifeCell Corporation ("LifeCell"):

**THE PARTIES**

**LifeNet Health**

1. LifeNet is a nonprofit corporation organized under 26 U.S.C. § 501(c)(3) and existing under the laws of the Commonwealth of Virginia and having a principal place of business in this judicial district at 1864 Concert Drive, Virginia Beach, Virginia 23453.

2. LifeNet's mission statement is "Saving Lives, Restoring Health." Founded in 1982 as the Eastern Virginia Tissue Bank, LifeNet is one of the world's most trusted providers of transplant solutions, from organ and tissue procurement to innovative bio-implant technologies and cellular therapies.

3. Each year, LifeNet facilitates the transplantation of over 400 organs in the United States and distributes over 400,000 allograft bio-implants to meet the needs of hospitals and

patients in the United States. An allograft is human donor tissue, such as skin, bone, tendon, and cardiovascular tissue, intended for transplantation in a human recipient.

4. LifeNet is also extensively involved in promoting and facilitating tissue-donation and bio-implant tissues. For example, LifeNet's Tissue Services Division is dedicated to training, educating, and maintaining relationships with more than 50 partners to promote tissue donation in their respective communities.

5. LifeNet also established its Skin and Wound Allograft Institute to ensure the processing and delivery of skin/dermal allograft bio-implants for U.S. burn centers.

6. In addition, LifeNet's Bio-Implants Division has pioneered technologies related to all aspects of the allograft bio-implant production process, including disinfection, decellularization (the removal of cellular elements from an allograft bio-implant), preservation, and sterilization.

7. LifeNet is also a member of several organizations related to tissue donation. For example, LifeNet is an accredited member of the American Association of Tissue Banks, and also a member organization of Donate Life America, a not-for-profit alliance of national organizations across the United States committed to increasing organ, eye, and tissue donation.

8. The patent asserted by LifeNet in this Complaint is a result of LifeNet's extensive research and development in the field of tissue and bio-implant technology.

#### **LifeCell Corporation**

9. Upon information and belief, LifeCell is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 95 Corporate Drive, Bridgewater, New Jersey 08807.

10. LifeCell is in the business of manufacturing, selling, and offering for sale various medical products including skin/dermal products under the brand names AlloDerm® RTM Ready to Use and Strattice™ Reconstructive Tissue Matrix.

11. Upon information and belief, AlloDerm® RTM Ready to Use is human dermal allograft, and Strattice™ Reconstructive Tissue Matrix is porcine (pig) skin xenograft. A xenograft is an animal tissue intended for transplantation in a human recipient.

### **JURISDICTION AND VENUE**

12. This action is a claim for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 271 *et seq.*

13. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1332, and 1338(a).

14. This Court has personal jurisdiction over LifeCell at least because LifeCell has substantial, continuing, and on-going contacts within the Commonwealth of Virginia and this judicial district, and LifeCell has sold and continues to sell the products at issue in this case in this Commonwealth and judicial district.

15. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and 1400(b) in that acts of patent infringement have occurred and are occurring within this judicial district.

### **FACTS**

#### **U.S. Patent No. 6,569,200**

16. On June 5, 2001, Lloyd Wolfenbarger, Jr., Robert K. O'Leary, and Billy G. Anderson ("the Inventors"), filed U.S. Patent Application No. 09/874,862 ("the '862

application”). The ’862 Application is a division of U.S. Patent Application No. 09/107,459, filed June 30, 1998, now U.S. Patent No. 6,293,970.

17. On August 29, 2002 the ’862 application published as U.S. Publication No. 2002/0120345.

18. On May 27, 2003, the ’862 application was issued by the U.S. Patent and Trademark Office (“USPTO”) as U.S. Patent No. 6,569,200 (“the ’200 patent”). A copy of the ’200 patent is attached as Exhibit A.

19. LifeNet is the assignee of all right, title, and interest in and to the ’200 patent and possesses all rights of recovery under the ’200 patent.

20. The ’200 patent is directed to, *inter alia*, “plasticized dehydrated or freeze-dried bone and/or soft tissue product[s] that do[] not require special conditions of storage,” and methods for producing the same. *See* Exhibit A, ’200 Patent Abstract.

21. As stated in the Abstract of the ’200 patent, “[t]he invention replaces water in the molecular structure of the bone or soft tissue matrix with one or more plasticizers allowing for dehydration of the tissue, yet not resulting in an increase in brittleness of the plasticized product, and resulting in compressive and/or tensile properties similar to those of normal hydrated bone. Replacement of the chemical plasticizers by water prior to implantation is not required and thus, the dehydrated bone or soft tissue plasticized product can be placed directly into an implant site without significant preparation in the operating room.” *Id.*

22. In 2007, LifeNet introduced Preservon® technology, its proprietary bio-implant tissue-preservation technology based on the ’200 patent family. It is an ambient temperature (room temperature) preservation method that simplifies the tissue-preparation and product

distribution processes and storage, saves valuable time in the operating room, and allows allograft tissue to retain its physical and biomechanical properties.

23. Starting in 2010 with the launch of its Oracell® dermal implant, LifeNet has marked its products incorporating the Preservon® technology with the '200 patent number.

**LifeCell's Infringing Products**

24. Upon information and belief, Defendant has been using, manufacturing, selling, and offering for sale a tissue product under the brand name Strattice™ Reconstructive Tissue Matrix ("Strattice").

25. Defendant makes the following claims about Strattice:

- "Strattice™ Reconstructive Tissue Matrix is an acellular reconstructive tissue matrix . . . derived from porcine dermis, which undergoes non-damaging proprietary processing that removes cells . . . ." Strattice Product Page (attached as Exhibit B) at 1;
- Strattice "requires no rehydration or orientation and can be stored at room temperature." *Id.*; and
- Strattice is a "a surgical mesh that is derived from porcine skin and is processed and preserved in a phosphate buffered aqueous solution containing matrix stabilizers," and that Strattice "should be stored in a clean, dry location at room temperature." Strattice Implantation Instructions (attached as Exhibit C) at 1, 2.

26. Upon information and belief, Strattice is a plasticized soft tissue graft suitable for transplantation into a human, as set forth in at least claims 1-4 of the '200 patent.

27. Upon information and belief, Defendant has been using, manufacturing, selling, and offering for sale a tissue product under the brand name AlloDerm® RTM Ready to Use ("AlloDerm RTU").

28. Defendant makes the following claims about AlloDerm RTU:

- AlloDerm RTU is "allograft human dermis, processed to remove cells while preserving biologic components and structure of the dermal matrix." AlloDerm RTU Instructions for Use (attached as Exhibit D) at 1;

- AlloDerm RTU storage is “at room temperature in its original packaging.” *Id.* at 3;
- “AlloDerm® RTM Ready to Use storage is at room temperature (8-30C /18-86F)” Alloderm Frequently Asked Questions Page (attached as Exhibit E) at 1; and
- AlloDerm RTU is “ready to use with a minimum 2-minute soak” and “saves substantial operating time by eliminating the rehydration step.” Alloderm Brochure (attached as Exhibit F) at 2.

29. Upon information and belief, Alloderm RTU is a plasticized soft tissue graft suitable for transplantation into a human, as set forth in at least claims 1-4 of the '200 patent.

30. Defendant has sold and offered for sale, and continues to sell and offer for sale AlloDerm RTU and Strattice (collectively, the “Infringing Products”) in this Commonwealth and this District, including but not limited to hospitals and other surgical centers.

**LifeCell's Knowledge of LifeNet's Invention and the '200 Patent**

31. On October 6, 2004, LifeCell employees Wendell Sun, Herbert D. Beniker, and David J. McQuillan filed U.S. Patent Application No. 10/959,780 (“the '780 application”), entitled “Methods of Storing Tissue Matrices,” and described in the Abstract as providing “methods of storing acellular tissue matrices in which a substantial portion of water in the matrices is replaced with a water-replacing agent, e.g., glycerol.” The '780 application published as U.S. Publication No. 2006/0073592.

32. In its '780 application, LifeCell asserted that its employees “have found that acellular tissue matrices (ATM) in which a substantial portion of water has been replaced with one or more water-replacing agents can be stored for extended periods of time at ambient temperature without substantial loss of structural or functional integrity.”

33. The USPTO disagreed with the characterization of the preservation technique as something LifeCell had discovered. On April 29, 2009 and on February 3, 2010, the Patent

Examiner responsible for reviewing the '780 application issued final rejections of the claims in LifeCell's application, as obvious under 35 U.S.C. § 103(a) in light of LifeNet's U.S. Patent No. 7,063,726 ("the '726 patent" or "Crouch"). The Examiner further rejected nine additional claims as obvious under 35 U.S.C. § 103(a) in light of the '726 patent in combination with other prior art.

34. LifeNet's '726 patent is a continuation-in-part of the '200 patent asserted herein. The '200 patent is listed on the face of the Crouch '726 patent as both a "Related U.S. Application" and a "Reference[] Cited".

35. The '200 patent and the Crouch '726 patent share a virtually identical disclosure of LifeNet's core Perservon® technology. Similar to the Abstract of the '200 patent, the Abstract of the '726 patent states, "[t]he invention provides a plasticized bone and/or soft tissue product that does not require special conditions of storage, for example refrigeration or freezing, exhibits materials properties that approximate those properties present in natural tissue, is not brittle, does not necessitate rehydration prior to clinical implantation and is not a potential source for disease transmission. Replacement of the chemical plasticizers by water prior to implantation is not required and thus, the plasticized bone or soft tissue product can be placed directly into an implant site without significant preparation in the operating room."

36. LifeCell appealed the Examiner's rejection of the claims in its '780 patent application to the USPTO's Board of Patent Appeals and Interferences ("Board").

37. On January 23, 2012, the Board affirmed the Examiner's final rejection of the claims in LifeCell's '780 application, indicating that "[in] view of the disclosure of Crouch, it would have been obvious to one of ordinary skill in the art to plasticize a cleaned and dehydrated bone or soft tissue graft with a water-based plasticizer and thereby arrive at the acellular tissue

matrix of claim 1 because Crouch expressly suggests the benefits of plasticized bone and tissue grafts and also expressly suggests water as a solvent for the plasticizer.” Board Decision at 6.

38. Based on the Board’s conclusion that LifeNet’s invention predated the subject matter claimed in the ’780 application, LifeCell abandoned its patent application.

39. On March 28, 2012, the USPTO issued a Notice of Abandonment confirming LifeCell’s decision to abandon its efforts to obtain a patent.

40. In light of the Patent Office’s rejection of LifeCell’s patent application, LifeCell was aware of LifeNet’s ’200 patent relating to plasticization of soft tissue grafts, capable of transplantation into a human, that can be stored for extended periods of time at ambient temperature without substantial loss of structural or functional integrity.

**COUNT I**  
**INFRINGEMENT OF THE ’200 PATENT**

41. Plaintiff LifeNet realleges and incorporates by reference paragraphs 1 through 40 of this Complaint as though fully set forth herein.

42. Defendant LifeCell has infringed and continues to infringe at least claims 1-4, 7, and 8 of the ’200 patent by, without LifeNet’s authority, manufacturing, causing to be manufactured, using, offering for sale, and selling in the United States at least the Infringing Products.

43. On information and belief, defendant LifeCell has been aware of the ’200 Patent, and its infringement thereof, since at least as early as 2009.

44. Despite its knowledge of the ’200 Patent and its infringement thereof, and despite an objectively high likelihood that its actions constituted infringement, Defendant LifeCell recklessly proceeded to infringe one or more claims of the ’200 Patent. LifeCell’s infringement therefore has been willful.



45. LifeNet has suffered monetary damages by reason of Defendant LifeCell's infringement of the '200 Patent.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff LifeNet requests relief against Defendant LifeCell Corporation as follows:

- (a) A judgment that Defendant has directly infringed the '200 Patent;
- (b) A judgment that Defendant's infringement has been willful;
- (c) A judgment and order requiring Defendant to pay damages under 35 U.S.C. § 284, including treble damages for willful infringement, together with costs and prejudgment and post-judgment interest;
- (d) A finding that this case is an exceptional case, and an order awarding Plaintiff its costs and reasonable attorney fees under 35 U.S.C. § 285; and
- (e) Any and all such other and further relief as the Court may deem appropriate.

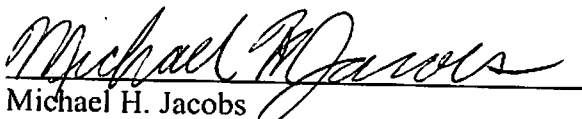
**JURY DEMAND**

LifeNet hereby demands a trial by jury on all issues triable to a jury.

Dated: September 6, 2013

Respectfully submitted,

**LIFENET HEALTH**

  
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